

REMARKS

Claims 1-6, 11-29, 31-32 and 34-55 are pending in the present application. Claims 1, 34, 40, 46 and 54 have been amended. Support for the amendments may be found at least in the specification at paragraphs [0040], [0041] and [0057] and in the Figures. No new matter was added. The amendments are presented in order to place the application in condition for allowance. Applicants respectfully request that the amendments be entered.

Applicants appreciate the helpful interview with the Examiner conducted March 21, 2007. The amendments and remarks presented herein are believed to resolve the remaining issues raised in the Office Action of January 9, 2007.

Reexamination of the application and reconsideration of the rejections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

Claims 1-6, 11-23, 25, 34-39 and 41-55 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Clark et al., U.S. Patent No. 5,259,835 (hereinafter "Clark"), in view of Ballance et al., U.S. Patent No. 6,439,789 (hereinafter "Ballance"). Applicants respectfully traverse this rejection.

Clark describes a wound closure device which employs a porous bonding member which receives a flowable adhesive which may be a cyanoacrylate. According to Clark, a flowable, fast setting, high strength adhesive is introduced into the bonding pad to bond the pad to the skin at opposite wound margins. *Column 1, lines 44-48.*

Ballance is directed to polymerizable 1,1-disubstituted ethylene monomer formulation applicators, applicator tips and applicator kits. The monomer may be surrounded by a container that may be engaged with an applicator tip. The applicator tip may have an internal cavity defined in an applicator tip body and a porous material member may be connected to the applicator tip body to be in fluid communication with the internal cavity. Bioactive agents, viscosity modifiers, initiators, inhibitors and/or stabilizers may be added to the applicator, preferably in or on the porous material member. *Abstract.*

Independent claim 1, as amended, is directed to a tissue bonding article comprising a flexible material, an adhesive substance applied covering substantially the entire bottom side of the flexible material and a polymerizable adhesive composition permeated throughout at least a portion of the flexible material.

Independent claim 34, as amended, is directed to a method of bonding tissue, comprising placing a flexible substrate over a section of tissue, wherein the flexible substrate

comprises a flexible material and an adhesive substance applied covering substantially the entire bottom side of the flexible material; applying a polymerizable adhesive composition over and substantially covering at least a portion of the flexible substrate; and allowing the polymerizable adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to the tissue.

Independent claim 46, as amended, is directed to a tissue bonding article, comprising a flexible material having a top side and a bottom side; an adhesive substance applied over at least a portion of the bottom side of said flexible material; and a polymerizable adhesive composition applied to the entire top side of said flexible material and permeated throughout at least a portion of said flexible material.

Independent claim 54, as amended, defines a method of bonding tissue, comprising placing a flexible substrate over a section of tissue, wherein said flexible substrate comprises a flexible material having a top side and a bottom side, and an adhesive substance applied over at least a portion of the bottom side of said flexible material; applying a polymerizable adhesive composition to and substantially covering the entire top side of the flexible material; and allowing the polymerizable adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to said tissue.

As discussed during the interview and explained in the Amendment filed November 21, 2006, the rejected claims are directed to articles and methods patentably distinct from the articles and methods of Clark or Ballance, alone or in combination. The rejected claims are patentable over Clark and Ballance alone or in combination, at least since Clark does not disclose or suggest the use of an adhesive substance applied covering substantially the entire bottom side of flexible material or disclose or suggest a polymerizable adhesive composition preferably applied to the entire top side of flexible material. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claims 24, 26, 28 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Clark and Ballance in view of Porzilli, U.S. Patent No. 5,336,209. Applicants respectfully traverse this rejection.

Claim 24, 28 and 29 are dependent on amended claim 1. Clark and Ballance are discussed above. Porzilli is directed to a protective wound bandage which allows for the ability to regulate and monitor oxygen flow to the injury site. Porzilli does not remedy the deficiencies of the combination of Clark and Ballance as described above since Porzilli does not disclose or suggest an adhesive substance applied covering substantially the entire bottom

side of a flexible material as claimed. In view thereof, Applicants respectfully request that the rejection as to these claims be withdrawn.

Claim 26 defines a tissue bonding article comprising a flexible material; an adhesive substance applied over at least a portion of a bottom side of the flexible material; and a polymerizable adhesive composition permeated throughout at least a portion of the flexible material, wherein the flexible material and the polymerizable adhesive composition are together biodegradable.

Clark does not disclose a flexible material and a polymerizable adhesive composition which are together biodegradable. Ballance also does not disclose such a combination. Porzilli describes a dressing which can be manufactured from biodegradable materials if so desired, states that the skin release adhesive covering strip 24 would be manufactured in a biodegradable material in the preferred embodiment, and indicates that the tear tab cover 14 is, in a preferred embodiment, manufactured from a translucent, opaque or clear biodegradable material. *Column 2, lines 13-14, 35-36 and 66-68*. However, Porzilli does not disclose or suggest a material wherein there is a flexible material and a polymerizable adhesive composition which are together biodegradable. Rather, Porzilli does not teach or suggest a biodegradable adhesive at all. In view thereof, none of the cited patents discloses or suggests the tissue bonding article defined in claim 26 and Applicants respectfully request that this rejection be withdrawn.

Claim 27 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Clark and Ballance. Applicants respectfully traverse this rejection.

Claim 27 is dependent on claim 1. For the reasons discussed above with regard to claim 1, a *prima facie* case of obviousness has not been made since the combination of Clark and Ballance would not have led one of ordinary skill in the art to the tissue bonding article defined in claim 1. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claim 40 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Clark and Ballance in view of VanDruff, U.S. Patent Application Publication No. 2002/0193721. Applicants respectfully traverse this rejection.

Amended claim 40 defines a method of bonding tissue. The method comprises placing a flexible substrate over a section of tissue wherein the section of tissue includes a wound to be closed and wherein the flexible substrate comprises a flexible material and an adhesive substance applied covering substantially the entire bottom side of the flexible

material. The method further comprises applying a polymerizable adhesive composition over and substantially covering at least a portion of the flexible substrate and allowing the polymerizable adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to the tissue. The placing of the flexible substrate comprises fixing a first lengthwise end of the flexible substrate to the section of tissue on a first lengthwise end of the wound; approximating edges of the wound; and fixing a second lengthwise end of the flexible substrate to the section of tissue on a second lengthwise end of the wound opposite the first lengthwise end of the wound.

VanDruff is directed to a wound closure grid tape apparatus and method. VanDruff is meant to provide external stitches in about the same spacing as traditional stitches that are held in place by cross-members and adhesion to the skin. The "stitch" can be thought of as being planar to the skin and deriving its strength to hold the wound closed from adhesion by cross-members at right angles to the wound, and also from the circuits created by the cross-members of the grid structure rather than by looping into and through the skin surface.

Paragraph [0032].

VanDruff does not remedy the deficiencies of the combination of Clark and Ballance as described above since VanDruff does not disclose or suggest an adhesive substance applied covering substantially the entire bottom side of a flexible material as claimed. In view thereof, Applicants respectfully request that the rejection be withdrawn.

For the foregoing reasons, claims 1-6, 11-29, 31-32 and 34-55 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

HUTCHISON LAW GROUP PLLC

Date: April 9, 2007

By: Mary B. Grant
Mary B. Grant
Registration No. 32,176

P.O. Box 31686
Raleigh, NC 27612
+1.919.829.9600